K010621

SEP - 4 2001

Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the proposed CP Medical Accu-Space™ device.

Manufacturer:

CP Medical, Inc.
2414 NE Pacific Avenue
Portland, OR 97232
PHONE: (503) 232-1555
FAX: (503) 230-9993

Contact Person:

Mary Ann Greenawalt, Director
Regulatory and Quality

Device Name:

Trade Name: Accu-Space™ Absorbable Seeding Spacers

Common Name: Accessory to applicator and accessory to radionuclide brachytherapy Source

Proprietary name: Accu-Space™ Absorbable Seeding Spacers

Classification: System, applicator, radionuclide, manual & Source, brachytherapy, radionuclide (accessory to)

Date Prepared: February 22, 2001

Predicate Device: The predicate devices to the CP Medical Accu-Space Seeding Spacers are the Surgical Specialties Collagen Spacer, K001765, the Worldwide Medical Technologies Seeding Spacers, K991344 and Indigo Medical, Inc. Seeding Spacers, K992262.

Device Description: The CP Medical Accu-Space Absorbable Seeding Spacer consists of absorbable spacer material, which is cut into a small cylindrical seed spacer utilized to provide space between the radionuclide seeds as they are implanted into the body.

Intended Use: The CP Medical Accu-Space Absorbable Seeding Spacers are single-use, absorbable seeds comprised of spacer material used to provide a predetermined space between radionuclide seeds for brachytherapy procedures. Absorbable Spacers are indicated for use in soft tissue or organ tissue but should not be used during cardiovascular or neurological procedures.

Indications: The CP Medical 's Accu-Space Absorbable Seeding Spacer device is intended to be used to maintain a predetermined space between radionuclide seeds during the introduction of the seeds into the body during Brachytherapy procedures. Absorbable spacers are indicated for use in soft tissue or organ tissue but should not be used during cardiovascular or neurological procedures.

Comparison of Technological Characteristics: The proposed device, the CP Medical Accu-Space Absorbable Seeding Spacer, is a seed spacer of absorbable material intended to maintain spacing between radioactive seeds when delivered by a *preloaded* seeding needle. Similarly, the predicate devices are intended to maintain spacing between radioactive seeds when delivered by a *preloaded* seeding needle.

end

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 2001

Ms. Mary Ann Greenawawlt
Director, Regulatory and Quality
CP Medical
P.O. Box 6724
PORTLAND OR 97208

Re: K010621
Accu-Space Absorbable Seeding Spacers
Dated: August 23, 2001
Received: August 28, 2001
Regulatory Class: II
21 CFR 892.5730/Procode: 90 KXK

Dear Ms. Greenawalt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K010621

Device Name(s): Accu-Space™ Absorbable Seeding Spacers

Intended Use(s) of the Device:

CP Medical's Accu-Space Absorbable Seeding Spacers are intended to be used to maintain a predetermined space between radionuclide seeds during the introduction of the seeds into the body during Brachytherapy procedures. Seeding Spacers are indicated for use in soft tissues or organ tissue but should not be used during cardiovascular or neurological procedures.

Please do not write below this line - continue on another page if necessary

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K010621

Prescription Use ✓ or Over-The-Counter Use _____

(per 21 CFR 801.109)